AUG 2 5 2003

K032341

510(k) Summary

As Required by 21 section 807.92 (c)

1-Submitter Name: Sota Precision optics, Inc
2-Address: 1073 North Batavia Street
Orange, CA 92867
3-Phone: 714-532-6100
4-Fax: 714-532-6107
5-Contact Person: Jay Mansour of Mansour Consulting LLC, on behalf of submitter
1308 Morningside Park Dr. Alpharetta, GA 30022. 770-777-4146
6-Date summary prepared: July 22nd, 2003
7-Device Trade or Proprietary Name: Claris i310
8-Device Common or usual name: Intra Oral Camera system and accessories
9-Device Classification Name: Unit, Operative, Dental
10-Substantial Equivalency is claimed against the following device:

- DIGITAL DOC from Digital Doc, Inc.
  510k # K981663

11-Description of the Device: **(For technical specifications, refer to the user manual)**
(Full listing and photos of accessories is available within this submission- refer to User Manual pages 22 and 23)

Claris i310 comprises of a light (0.1 lbs), small (8"x0.86"), and ergonomic handpiece along with a docking station.

The handpiece consists of a focusing mechanism and a capture button to assist the doctor in taking intraoral or full face images of the patient.

The handpiece connects to a docking station via a cable. The docking station in turn can connect directly to a monitor, PC, or a printer via a S-Video or a standard composite connection.

Claris i310 is also available in a wireless option.

It uses high definition imaging (494 lines/inch) to capture images at 60 degrees field of view.

Images may be stored using third party software vendors.

Claris i310 includes also an optional footswitch.

12-Intended use of the device: (refer to FDA form attached)

Claris i310 intra oral camera system and accessories is indicated for use to provide the dentist and the patient with a view of the mouth before and after the dental procedure, which assists the dentist in describing the dental procedure being performed as well as showing the results.

13-Safety and Effectiveness of the device:

This device is safe and effective as the other predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with other predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached. **Refer to the detailed explanations within the main submission.**

FDA file reference number	510k # K981663
Attachments inside notification submission file	510k FDA website print out
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Identical
Target population	Identical
Design	Similar
Materials	Similar
Performance	Similar
Sterility	Not Applicable
Biocompatibility	Similar
Mechanical safety	Similar
Chemical safety	Similar
Anatomical sites	Identical
Human factors	Similar
Energy used and/or delivered	Similar
Compatibility with environment and other devices	Similar
Where used	Identical
Standards met	Similar
Electrical safety	Similar
Thermal safety	Similar
Radiation safety	Similar

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 5 2003

Sota Precision Optics, Incorporated
C/O Mr. Donald J Sherratt
Responsible Third Party Official
Intertek Testing Services
70 Codman Hill Road
Boxborough, Massachusetts 01779

Re: K032341
Trade/Device Name: Claris i310 Intra Oral Camera System and Accessories
Regulation Number: 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: August 15, 2003
Received: August 18, 2003

Dear Mr. Sherratt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use statement

510(k) Number (if known): K032341

Device Name: Claris i310 Intra Oral Camera System and Accessories

Indications For Use:

Claris i310 intra oral camera system and accessories is indicated for use to provide the dentist and the patient with a view of the mouth before and after the dental procedure, which assists the dentist in describing the dental procedure being performed as well as showing the results

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032341

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)